EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)	C.A. No. 05-356-KAJ (consolidated)

OPENING EXPERT REPORT OF DR. HOWARD M. FILLIT

I. ACADEMIC AND PROFESSIONAL QUALIFICATIONS

A. Current position

1. I am the founding Executive Director and member of the Board of Directors of the Institute for the Study of Aging (ISOA) and the Alzheimer's Drug Discovery Foundation (ADDF). ISOA and ADDF fund drug discovery and development for Alzheimer's Disease in academia and the biotechnology industry. I am also a Clinical Professor of Geriatrics and Medicine, and Professor of Neurobiology at the Mount Sinai Medical Center in New York and an Associate Physician at the Rockefeller University Hospital.

2. I have 25 years of experience in the area of Alzheimer's Disease drug discovery and development. During that time, I have worked with many pharmaceutical and biotechnology companies and non-profit organizations on clinical development in the Alzheimer's Disease area, and I draw upon my experience in submitting this report.

B. Background

3. I am a physician and scientist by training and background. I received my B.A. in Neurobiology from Cornell University in 1970 and my M.D. from SUNY-Upstate Medical

Center in 1974. I subsequently completed an internship and residency in internal medicine at the Beth Israel Medical Center, a postdoctoral fellowship in immunology at The Rockefeller University, and a fellowship in Nephrology at the New York Hospital-Cornell Medical Center.

4. I have held academic positions in geriatric medicine at the New York Hospital-Cornell Medical Center, SUNY-Stonybrook School of Medicine, the Mount Sinai School of Medicine, and The Rockefeller University. I have held clinical positions in geriatric medicine at the Jewish Institute for Geriatric Care, the New York Hospital, and the Mount Sinai Medical Center.

5. I am licensed to practice medicine in New York. I am certified by the American Board of Internal Medicine, the American Board of Medical Laboratory Immunology, and the National Board of Medical Examiners. I am also certified by the American Board of Internal Medicine in Geriatric Medicine.

6. I am a fellow of several professional organizations related to the practice of and research in medicine: American College of Physicians, American Geriatrics Society, the Gerontological Society of America, and the New York Academy of Medicine.

7. I have served as chair or member of advisory boards or as consultant to a wide range of health care companies, including: Neurotrax, Inc., Neuromolecular, Inc., Advanced Monitored Caregiving, Inc., Allon Therapeutics, Neurochem, Inc., Healthcare Dimensions, Inc., Zapaq, Sanofi-Aventis Pharmaceuticals, AstraZeneca Pharmaceuticals, Novartis, Janssen, Forest Laboratories, Eisai, Pfizer and the Memory Fitness Institute. For Janssen, I participated in an advisory board on Razadyne post-approval pharmaco-economic studies.

C. Experience with Clinical Trials and Drug Development

8. I have more than 25 years of experience in the development of drug therapies for Alzheimer's Disease, including clinical and preclinical phases. Around 1980, I founded the

Alzheimer's Clinic at Rockefeller University and, the next year, began a pilot study investigating the use of estradiol for post-menopausal women with Alzheimer's Disease.

9. For several years, I served on the Consultants Committee of the Woman's Health Initiative Memory Study ("WHIMS"). The study was a large, population-based study of the use of Premarin in post-menopausal women. The study aimed at answering the question whether the use of Premarin could prevent Alzheimer's Disease. I helped design the study and evaluate data from the study.

10. I chair a scientific advisory board for Neurochem, Inc. I started working with the company when it had a few employees. The company is now a $600 million company involved in Phase III trials of Alzhemed for treatment of Alzheimer's Disease. Alzhemed is a small-molecule inhibitor of amyloid aggregation and fibrillation. I advised on the drug development, including pre-clinical proof of concept and clinical trial design.

11. The Institute for the Study of Aging has given away over $25 million to 140 drug discovery and development programs in 12 countries since 1998. I have evaluated almost 800 proposals in connection with this grant program.

12. I have helped start two biotechnology companies that were pre-clinical companies dedicated to Alzheimer's Disease. One of these companies, Allon Therapeutics, is now in Phase II testing and was recently voted one of the ten best biotech companies in Canada. ISOA provided start-up capital for this company based on its pre-clinical research. The other company, Zapaq, is a leader in the development of beta-secretase inhibitors, based on its chemistry. I am currently helping the company to design its clinical program.

13. My biographical information and *curriculum vitae* are attached hereto as Attachment A.

D. **Prior testimony**

14. In the last four years, I have been deposed once. I was deposed in 2005 in connection with an insurance case, Hammermueller v. American Equity, Case No. INC037361, filed in the Superior Court for the State of California, County of Riverside.

E. **Compensation**

15. For my work in connection with this matter, I am being compensated at my usual rate of $550 per hour. My compensation is not linked in any way to the outcome of this litigation.

II. SCOPE OF OPINION

16. I have been asked to review the assertions of invalidity made by the defendants in this litigation concerning patent at issue, U.S. Patent No. 4,663,318 (the "'318 patent").

17. I was informed about the patent law concepts of "objective considerations of non-obviousness" and was asked to form an opinion about whether certain objective considerations support the non-obviousness of the invention claimed in the'318 patent. Specifically, I was asked, based on my area of expertise – drug discovery and development in the Alzheimer's area – to focus on two objective considerations: unexpected benefits of galantamine and skepticism of others skilled in the art.

18. In reviewing the defendants' assertions and forming the opinions stated in my report, I relied upon my experience in the field of drug discovery and development, my knowledge of the relevant literature and state of the art, and also reviewed the materials set forth in Attachment B.

III. BACKGROUND

A. The '318 Patent

19. I understand that only two claims of the '318 patent are at issue in this litigation: claim 1 and claim 4. Furthermore, I understand that the defendants have stipulated to the infringement of these claims, and that only the validity of these claims is being litigated.

20. I understand that Claim 1 of the patent claims: "A method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof."

21. I understand that Claim 4 of the patent claims: "A method according to claim 1, wherein said administration is oral and is in the range 10-2000 mg per day."

22. I understand the claims of the '318 patent to be directed to the treatment of Alzheimer's Disease, whether pre-senile or Senile Dementia of the Alzheimer's Type, using therapeutic doses of galantamine or its pharmacologically acceptable salts, including galantamine hydrobromide. I understand "treatment" to include the alleviation of some or all of the symptoms of Alzheimer's Disease, particularly the cognitive loss that is a cardinal feature of the disease.

23. I also understand that the application for the '318 patent was filed in the U.S. Patent and Trademark Office on January 15, 1986, and I have been asked to consider the obviousness of the invention as of that date.

B. Alzheimer's Disease

24. Today, Alzheimer's Disease is understood to be a progressive, degenerative disorder of the brain that occurs in the elderly. The manifestations of the disease include memory loss and impairment of thinking, judgment, and communication skills. Ultimately, the

disease produces behavioral and personality changes, such as paranoia, delusions, and apathy. The disease impairs activities of daily living and places an enormous strain on the caretaker and family of the patient living with Alzheimer's Disease.

25. The disease is characterized by "plaques" and "neurofibrillary tangles" that disrupt neurotransmitter systems in the brain. Plaques are formed by a protein called amyloid precursor protein or APP that is present in certain normal brain cells. In Alzheimer's, an enzyme metabolizes or clips off the ends of the APP, and the middle or "beta" section is released outside the nerve cell. These beta amyloid pieces tend to consolidate, or clump together, creating plaques, which grow and disrupt transmission of impulses through surrounding nerve junctions. The precise cause of these plaques and of tangles remains unclear.

26. However, this has not always been the understanding of Alzheimer's Disease. In order to provide context to the skepticism surrounding the efficacy of the invention here, I have summarized the disease as it has been understood (or misunderstood) historically.

IV. PERCEPTION OF AD IN DRUG DISCOVERY AND DEVELOPMENT IN 1986

A. Historical perspective on Alzheimer's Disease as a Disease

27. When Alzheimer's Disease was first discovered in 1906, it was considered a rare disease of middle-age. Senility – loss of mind with aging – was still considered a normal part of the aging process.

28. These conceptions of Alzheimer's Disease and senility changed in the late 1960s, when work in the United Kingdom established that senility was not a normal part of aging but instead was a disease (e.g., Blessed, G. et al., The Association Between Quantitative Measures of Dementia and of Senile Change in the Cerebral Grey Matter of Elderly Subjects, British Journal of Psychiatry 114:797-811 (1968)).

29. This work compared the brains at autopsy of a group of elderly people who were senile with a group of elderly people who were not senile. The researchers found that the brains of those who were senile had the changes in the brain described by Alzheimer, namely plaques and tangles.

30. As a result, senility became Senile Dementia of the Alzheimer's Type – "SDAT."

31. The National Institute on Aging (NIA) was founded in 1974 by Dr. Robert Butler. The founding of this institute initiated the growth in attention and research in Alzheimer's Disease that occurred in the late 1970's.

32. Dr. Butler published "Why Survive?: Being Old in America" which was awarded the Pulitzer Prize in 1976. His book helped bring Alzheimer's Disease as an epidemic among the elderly and a threat to our society to the attention of Congress and the American people, beginning three decades of focus on the disease.

B. Status of Drug Development in 1986

33. By 1986, Alzheimer's Disease was recognized as a progressive, irreversible, fatal disease by experts in the field. However, there were no approved drugs for treating Alzheimer's Disease. The first drug approved by FDA for treatment of Alzheimer's Disease, tacrine, was not approved until almost 8 years later, in the fall of 1993.

34. The vast majority of clinicians working on the disease at the time were trained in an era when Alzheimer's Disease was still viewed as a rare disorder of middle age. Those who were aware of the disease viewed it as untreatable. At most, clinicians could only offer care management.

35. In 1986, I was running a lab on Alzheimer's Disease at Rockefeller University and was the director of the Alzheimer's Clinic at Rockefeller, which I had founded in the early

1980s. At the time, I was pessimistic and had little hope that an effective treatment for Alzheimer's Disease would be developed in my lifetime. There were many ideas available, but it seemed highly unlikely that any one of them would succeed.

V. SKEPTICISM IN THE DRUG DISCOVERY AND DEVELOPMENT COMMUNITY

36. In 1986, there were many theories about treatment for Alzheimer's Disease but no proven therapies. Even among those working on drug discovery and development, the prevailing view was one of skepticism towards the likelihood of any particular approach succeeding. Science supported a wide range of possible approaches to treatment, while experience did not demonstrate efficacy for any of them.

37. For example, a perceived link between Alzheimer's Disease and reduced blood flow to the brain led some to believe that improving blood flow would treat the disease and improve cognition. In the 1980s and early 1990s, many of the drugs tried for Alzheimer's disease were vasodilators – drugs that open or dilate the arteries –but these proved ineffective. Examples of vasodilators that were tried unsuccessfully include papaverine, cyclandelate, isoxuprine, and pentoxyfylline. (e.g., Swaab, D.F., and E. Fliers, "Clinical Strategies in the Treatment of Alzheimer's Disease," in Progress in Brain Research, vol. 70, 413-27 (Elsevier Science Publ. 1986)) Relatedly, a number of anti-coagulants, such dicumarol and warfarin, were tried in an attempt to improve blood flow, specifically to prevent cerebral emboli or thrombosis. None of these attempts succeeded.

38. The lesson learned from these failures was the limit of "logic" in developing a treatment for Alzheimer's Disease and the need for proven treatment concepts. As Swaab and Fliers warned in their 1986 publication,

> Repeatedly, ideas about the etiology of Alzheimer's disease have been adapted immediately to new disciplines or insights that developed in neurosciences. Thus changes in hormone levels,

> blood supply, metabolism, and transmitters have been pinpointed as possible causes of brain aging and Alzheimer's disease. Subsequently, a 'new and promising' therapy was claimed to have a 'rational' basis and was tried out on Alzheimer patients. This history might make us less optimistic about all the ongoing clinical trials, and even more convinced about the necessity of fundamental research in Alzheimer's disease before a therapy with a reasonable chance of success will ever succeed in being developed. (Swaab & Fliers, p. 413)

39. There were, in fact, considerable reasons to be skeptical of cholinesterase inhibitors at that time. First, the trials of cholinesterase inhibitors as of January 1986 were either unsuccessful or produced equivocal results, with reported improvements in patients perceived as inconsistent or fleeting and at best marginal. None of the cholinesterase inhibitors tried to that point appeared to provide clinically meaningful or consistent improvement, and those trials were certainly not seen as a proof of concept concerning cholinesterase inhibitors. In the view of the drug discovery and development community, those trials had not yet found even a single successful compound for treating Alzheimer's Disease, let alone establishing the efficacy of a class of drugs.

40. Second, there was a serious concern about side-effects. Cholinesterase inhibitors have considerable undesirable effects on the brain and the rest of the body, and at best would be expected to have a very narrow therapeutic window. There were substantial concerns that therapeutic doses of this drug class would not be tolerable to patients.

41. Third, a cholinesterase inhibitor approach appeared too narrow. In Alzheimer's Disease, nerve cells die in various parts of the brain and various brain systems. Alzheimer's Disease therefore affects broad aspects of brain function across multiple domains of cognition, not just memory and learning. The "Five A's of Alzheimer's" provide an illustration of the various brain functions affected by the disease:

- Amnesia (loss of memory);

- Agnosia (a failure to recognize or identify objects or people despite intact sensory function);
- Aphasia (loss of language);
- Apraxia (an inability to carry out complex motor activities despite intact motor and sensory function);
- Abstraction.

42. Each of these functions is performed in a different part of the brain. In 1986, there was no reason to believe that improving cholinergic function would have a beneficial effect on such a broad range of dysfunctions.

43. To put it more broadly, there are many cognitive dysfunctions with Alzheimer's Disease (in addition to many emotional dysfunctions) which are part of the biology of the disease. Even if one accepted the idea that cholinesterase inhibitors could improve working memory, one would not necessarily be led to believe that cholinesterase inhibitors could also provide any meaningful clinical benefit in terms of activities of daily living.

44. For a product to be an effective treatment for Alzheimer's Disease, it must provide a meaningful clinical benefit to patients. It was not clear whether improving one aspect of cognition, say working memory, would provide a meaningful clinical benefit in the treatment of Alzheimer's Disease, which profoundly affects so many cognitive domains and instrumental and basic activities of daily living. As of January 1986, the trials conducted to that point on cholinesterase inhibitors did not even approach this issue, let alone provide meaningful evidence of any benefit in an Alzheimer's patient's activities of daily living.

45. In short, it is my opinion that those in the drug discovery and development community were skeptical that cholinesterase inhibitors would prove a successful treatment for Alzheimer's Disease. In fact, I myself was skeptical at the time of that approach. In 1986, I published a paper, together with colleagues at Rockefeller University and the Cornell Medical

Center, expressing skepticism of cholinesterase inhibitors and proposing an alternative approach to treatment. Specifically, we wrote that:

> Most current treatment strategies in senile dementia-Alzheimer's type (SDAT) are predicated upon the deficit in central cholinergic transmitter activity that has been established in this disorder. Attempts to correct this deficit have been made, either by supplementation of cholinergic agonist precursors or by the inhibition of acetylcholine degradation. **For the most part, these attempts have been unsuccessful or equivocal, although some benefit has been ascribed to cholinesterase inhibitors. Dosages of the latter agents are limited by their low therapeutic ratio.** An alternate approach to modifying this central cholinergic deficit could involve the use of hormones, acting via genomic mechanisms, to increase levels of enzymes necessary for neurotransmitter synthesis.

Fillit, H., *et al.*, "Observations in a Preliminary Open Trial of Estradiol Therapy for Senile Dementia-Alzheimer's Type," Psychoneuroendocrinology 11:337-345 (1986) (emphasis added; citations omitted).

46. Similarly, in their 1986 survey of Alzheimer's treatments, Swaab and Fliers were also critical of such an approach:

> [I]t is not realistic to expect that one can mimic the complex and naturally occurring spatial-temporal fluctuations of a local transmitter release by means of global administration of chemical substances. In addition, one can never replace the complete integrating function of a neuron by straightforward administration of neurotransmitter. These are some of the considerations ... which call for skepticism regarding the potentialities of neurotransmitter 'replacement' therapy, whether in the case neuropeptides or for other putative neurotransmitters. (Swaab and Fliers, at p. 421).

B. A Preference for Other Approaches to Treat Alzheimer's Disease

47. Even among those pursuing a cholinergic approach, many researchers remained skeptical of cholinesterase inhibitors and preferred other approaches. An approach that appeared particularly attractive at the time was muscarinic agonists, which unlike cholinesterase

inhibitors or choline precursors did not require a functioning presynaptic cholinergic neuron. The logic favoring agonists was well summed up by Raymond Bartus, a highly regarded neuropsychopharmacologist whose responsibility at Lederle Laboratories was to find pharmacologic treatments, who along with several coauthors published a review in 1985 advocating muscarinic agonists as the most promising avenue for cholinergic therapy. Bartus, R., *et al.*, "The Cholinergic Hypothesis: A Historical Overview, Current Perspective, and Future Directions," in Memory Dysfunctions: An Integration of Animal and Human Research from Preclinical and Clinical Perspectives, Annals of the New York Academy of Sciences vol. 444, 332-58 (1985). In their words,

> Recent reports that degeneration of cholinergic forebrain nuclei may account for the loss of CAT activity in Alzheimer's patients provides additional impetus for studies with cholinergic agonists. That is, if one assumes this degeneration plays a major role in the cognitive symptoms of the disease, then the most effective means available to treat the deficit would be to compensate for the loss of cholinergic input to the cortex and hippocampus by stimulating the surviving postsynaptic cholinergic receptors. (page 342)

48. Considerable efforts were devoted to development of a muscarinic agonist as a treatment for AD, including not only arecoline, but also Eli Lilly's xanomeline, which that company pursued through Phase III clinical trials. However, despite over twenty years of efforts, no agonist has yet succeeded as a treatment for AD.

49. At the same time, other researchers, myself included, believed that hormone replacement therapy, such as estrogen or estradiol, provided a more promising avenue as a treatment for Alzheimer's Disease, a belief bolstered by the clinical evidence available at the time. Estrogen therapy did not appear to suffer from at least two of the limitations that appeared to undermine cholinesterase therapy – namely, an unduly narrow therapeutic index and an overly narrow neurochemical effect. As to therapeutic index, estradiol appeared tolerable and effective

at "relatively low dosages." (p. 341) As to neurochemical focus, estradiol appeared to have broader beneficial affects on the brain, enhancing both cholinergic function and other affected neurochemical systems. As we wrote in 1986:

> Although it is possible that estradiol exerts a clinical effect on cognition and emotion by enhancing cholinergic function, estrogen also affects other neurotransmitter systems. In this regard, neurochemical studies have demonstrated that other neurotransmitter systems in addition to the cholinergic system may be involved in SDAT. Thus, changes in multiple neurotransmitter systems may be associated abnormal brain function in our aged demented subjects, and these neurotransmitter systems may have been directly or indirectly modulated by estradiol via genomic and non-genomic mechanisms. (p. 341-42; citations omitted)

50. I was involved in clinical trials that tested the possible benefits of estradiol treatment in postmenopausal women with SDAT. Some patients in our study showed significant improvement in measures of attention, orientation, mood, and social interaction – in other words, improvement in a broad range of functions affected by Alzheimer's Disease. In a review of our work published in 1986, as part of the influential series of books edited by Thomas Crook, Raymond Bartus, Steven Ferris, and Samual Gershon, we found that hormone therapy appeared promising both to "enhanc[e] the neurotransmitter function in pertinent cortical systems" and potentially to slow the disease through a neuroprotective function. We concluded that "estrogen therapy for AD has a rational scientific basis;" that "estradiol may be of value in the symptomatic treatment of a subgroup of postmenopausal women with AD;" and finally that "[c]ontrolled clinical research trials [were] needed to establish and to further define a potential therapeutic role for estrogens and other hormones in AD and related dementias." (Fillit, H., *et. al.*, "Hormonal Therapy for Alzheimer's Disease" in Crook, T., *et al.*, eds., Treatment Development Strategies for Alzheimer's Disease 311-336, at p. 329-30 (1986).)

51. Unfortunately, it ultimately was shown that neither estradiol nor estrogen is a treatment for Alzheimer's Disease.

VI. UNEXPECTED BENEFITS OF GALANTAMINE

52. As indicated above, I believe it was unexpected in 1986 that galantamine would prove a successful treatment for Alzheimer's disease at all. However, not only has galantamine proved such a treatment, since that time we have learned that the drug (and perhaps the other approved cholinesterase inhibitors) also improves a surprisingly wide range of cognitive functions, such as attention, apathy, and executive function. This broad range of improvements in cognitive functions is associated with an overall improvement in clinical global assessments and in activities of daily living. In other words, galantamine improves both cognition and function in patients with Alzheimer's Disease, though the pathways for these improvements is unclear. Amelioration of activities of daily living provides meaningful clinical benefit, which is the ultimate test of therapy in Alzheimer's Disease.

53. In addition, galantamine also appears to treat many of the non-cognitive symptoms associated with the disease, including neuropsychiatric symptoms measured by the Neuropsychiatric Inventory, such as delusions, hallucinations, agitation, depression, anxiety, irritability, and aberrant motor behaviors. Treatment of these symptoms improves the lives not just of Alzheimer's patients, but also their caregivers by reducing their burden.

54. This breadth of improvement in the functions of Alzheimer's Disease patients was not an expected benefit of galantamine treatment in January 1986. At that time, the drug discovery and development community was focused on trying to treat the cognitive aspects of Alzheimer's Disease, and there was very little understanding of how such treatment would impact the overall function of Alzheimer's patients.

55. The breadth of therapy provided by galantamine may result in part from the benefits – unsuspected back in 1986 – of improving cholinergic function in the brain through inhibition of cholinesterase. It is now believed that galantamine has a second mechanism of action, in addition to cholinesterase inhibition, to allosterically modulate the nicotinic receptors in the brain, increasing their response to stimulation by acetylcholine. The efficacy of galantamine may depend on its multiple mechanisms of action, including ones not yet discovered. For example, a recent head-to-head trial of galantamine and donepezil showed greater long-term benefits for galantamine (only galantamine maintained cognition at baseline levels after 1 year of treatment), with the difference being particularly pronounced for attention and executive function, cognitive attributes thought to be linked to stimulation of neuronal nicotinic receptors. (Wilcock, G., *et al.*, "A Long-Term Comparison of Galantamine and Donepezil in the Treatment of Alzheimer's Disease," Drugs Aging 2003; 20:777-89.) Though only a small pilot study, the results are supportive of the proposition that galantamine may have surprising long-term benefits as a result, at least in part, of its dual mechanism.

Dated: 7/24/06

Dr. Howard M. Fillit

ATTACHMENT A

Howard Martin Fillit, MD

Howard Martin Fillit, MD

Biography

Howard Fillit, MD, is the founding Executive Director and member of the Board of Directors of the Institute for the Study of Aging (ISOA), a private foundation based in New York City established by the Estee Lauder Trust. The Institute employs a venture philanthropy model to fund drug discovery and development for Alzheimer's disease in academia and in the biotechnology industry. Since inception in 1998, ISOA has provided over $25MM to over 140 academic and biotechnology programs in 12 countries. In 2004, Dr. Fillit founded the Alzheimer's Drug Discovery Foundation, a public charity affiliate of the Institute, to develop innovative partnerships with individuals, foundations, industry and government to advance drug discovery for Alzheimer's disease.

Dr. Fillit is a physician-scientist (geriatrician and neuroscientist) with career experience in academia and industry. From 1995-1998, he was the Corporate Medical Director for Medicare at NYLCare Health Plans (previously a division of New York Life), with enrollment of over 125,000 lives in 8 regional US markets. Prior to 1998, Dr. Fillit had a distinguished career in academic medicine. He continues to hold the title of clinical professor of geriatrics, medicine and professor of neurobiology at The Mount Sinai Medical Center (NY). He is a fellow of the American Geriatrics Society, the American College of Physicians, the Gerontological Society of America, and the New York Academy of Medicine. He is the author or co-author of over 200 scientific and clinical articles, abstracts, and books including the leading international Textbook of Geriatric Medicine and Gerontology.

Dr. Fillit is internationally recognized and has received numerous awards and honors. In 1999, he received the Rita Hayworth Award for lifetime achievement from the Alzheimer's Association. He is the Chairman of the Scientific Advisory Board for Neurochem, Inc. (NSDQ:NRMX). He is also a member (as observer) of the Board of Directors of Zapaq, Inc., and a member of the Scientific Advisory Board for Allon Therapeutics (TSX:NPC), both biotechnology companies co-founded by ISOA. He also serves on the Advisory Board of Healthcare Dimensions, Inc., an innovator in creating and managing wellness programs for the elderly, with current enrollment of over 2 million managed care lives in the United States. He has given hundreds of speeches throughout the world and has served as a consultant to numerous individuals, managed care organizations, health care systems, pharmaceutical and biotechnology companies and investment firms.

RESUME

FOUNDING EXECUTIVE DIRECTOR and MEMBER, BOARD OF DIRECTORS THE INSTITUTE FOR THE STUDY OF AGING, INC., NEW YORK, NY (1998-PRESENT) FOUNDING EXECUTIVE DIRECTOR and MEMBER, BOARD OF DIRECTORS ALZHEIMER'S DRUG DISCOVERY FOUNDATION, NEW YORK, NY (2004-PRESENT)

ISOA's mission is to catalyze and fund the discovery and development of new drugs for the treatment of cognitive aging and Alzheimer's disease employing an innovative business model of biomedical venture philanthropy. ISOA has provided over $25M to over 145 academic and industry drug discovery programs in 12 countries. ISOA investigators have screened millions of compounds, created new classes of therapeutic agents, identified hundreds of new leads, filed numerous patents and completed several licensing agreements. ISOA's Biotechnology Program has provided over $5M in funding to 16 early stage biotechnology companies that have subsequently raised over $285M in follow-on funding. The ISOA Biotechnology Founder's Program has provided founding capital and strategic management assistance to start 2 biotechnology companies. ISOA has also raised over $2.5MM in external funding primarily from the pharmaceutical industry for its Outcomes Research Program, focused on the health economics and pharmacoeconomics of Alzheimer's disease. Finally, through consulting projects with the pharmaceutical and biotechnology industry, managed care organizations, and health care providers, Dr. Fillit has worked to improve the care of the elderly through program development, quality improvement and education. In 2004, Dr. Fillit led the founding of the Alzheimer's Drug Discovery Foundation, a public charity, created to enable public participation in accelerating and funding drug discovery for Alzheimer's disease.

CLINICAL PROFESSOR OF GERIATRICS, MEDICINE PROFESSOR OF NEUROBIOLOGY THE MOUNT SINAI MEDICAL CENTER, NEW YORK, NEW YORK (1987-present)

From 1987 to 1995, Dr. Fillit pursued an academic career at Mount Sinai, achieving full tenured professorships in geriatricis, medicine and neurobiology. During this period, Dr. Fillit had numerous clinical, research, education and administrative responsibilities. Among these, he was Chief of Services for the Geriatric Evaluation and Treatment Unit at Mount Sinai Hospital; operated a private faculty practice; headed a research neurobiology laboratory for the study of Alzheimer's disease that was successfully funded through private foundations and the National Institute of Health; and participated in numerous administrative committees of the medical center. Dr. Fillit is currently a clinical professor of geriatrics and medicine, and professor of neurobiology at Mount Sinai.

CORPORATE MEDICAL DIRECTOR FOR MEDICARE NYLCARE HEALTH PLANS, INC., THE NEW YORK LIFE INSURANCE COMPANY NEW YORK, NY (1995-1998)

During Dr. Fillit's tenure, NYLCare Health Plans, a subsidiary of The New York Life Insurance Company, was one of the ten largest managed care organizations in the United States, serving over 125,000 elderly individuals in 8 regional markets through Medicare risk programs and over 2.5 million individuals in 50 states through its HMO, PPO and indemnity health care products. Dr. Fillit's accomplishments at NYLCare include: implementation of a *high risk screening* program for over 100,000 members in multiregional health plans; design and implementation of *geriatric care management and disease management programs*; implementation of *quality improvement programs* used for successful NCQA accreditation; development of *effective utilization management* strategies and a comprehensive continuum of care; *education and training* programs for physicians and other providers, including clinical practice guidelines; service on committees for Technology Assessment, Legislative Strategy, and Pharmacy and Therapeutics; for business development, representing the company's Medicare programs to the pharmaceutical industry, manged care organizations and other vendors; presentations at national meetings and participation on national advisory boards to assist NYLCare in developing and promoting

its' product and educating audiences in the benefits and contributions of managed care to the public health.

APPENDIX

ACADEMIC POSITIONS

THE ROCKEFELLER UNIVERSITY (2003-present)
Associate Physician, The Rockefeller Univeristy Hospital

THE ROCKEFELLER UNIVERSITY, NY, NY
LABORATORY OF BACTERIOLOGY AND IMMUNOLOGY (1976-1991)
Adjunct Faculty (1987-1991); Assistant Professor (1982-1987); Associate Physician (1982-1987); Guest Investigator (1979-1982); Visiting Associate Physician (1979-1982);
Assistant Physician(1976-1979)

DIVISION OF GERIATRICS AND GERONTOLOGY
DEPARTMENT OF MEDICINE
NEW YORK HOSPITAL - CORNELL MEDICAL COLLEGE, NY, NY (1982-1987)
Adjunct Assistant Professor of Medicine (1982-1987)
Clinical Affiliate and Teaching Attending Geriatrician (1982-1987)
Attending Geriatrician (1982-1989), Dewitt Nursing Home

JEWISH INSTITUTE FOR GERIATRIC CARE
LONG ISLAND JEWISH-HILLSIDE MEDICAL CENTER
NEW HYDE PARK, NEW YORK
Attending Geriatrician and Director of Research (1981-1982)

DEPARTMENT OF MEDICINE
SUNY-STONYBROOK MEDICAL COLLEGE
STONY BROOK, NY
Assistant Professor of Medicine (1981-1982)

THE ROGOSIN KIDNEY CENTER, DIVISION OF NEPHROLOGY
DEPARTMENT OF MEDICINE
NEW YORK HOSPITAL-CORNELL MEDICAL CENTER, NY, NY
Instructor in Medicine (1980-1981)
Clinical Affiliate in Nephrology (1980-1981)

POSTDOCTORAL TRAINING

Fellow in Nephrology (1979-1980), The Rogosin Kidney Center, Division of Nephrology, Department of Medicine, New York Hospital-Cornell Medical Center, NY, NY

Postdoctoral Fellow in Immunology (1976-1979), Laboratory of Bacteriology and Immunology The Rockefeller University, NY, NY

Intern and Resident in Internal Medicine (1974-1976), Department of Medicine
Beth Israel Medical Center, Mount Sinai School of Medicine, NY, NY

EDUCATION

M.D.: SUNY-Upstate Medical Center, Syracuse, New York (1970-1974)
B.A. *cum laude* with Honors in Neurobiology, Cornell University, Ithaca, New York (1966-1970)

CERTIFICATION

Diplomate in Geriatric Medicine, American Board of Internal Medicine (1987)
Recertified in Geriatric Medicine, 1999-2009
Diplomate of the American Board of Internal Medicine (1981)
Diplomate of Medical Laboratory Immunology (1985), American Academy of Microbiology
Diplomate of the National Board of Medical Examiners (1975)

LICENSURE

Professional Licensure in New York State (1976-present)

HONORS

Listed in "America's Top Doctors" (2005)
Listed in "Best Doctors in America" in the United States (2002-present)
Stein Annual Lecturer, Jewish Home and Hospital Lifecare System (2004)
America's Registry of Outstanding Professionals (2003)
International Biographical Center Scientist of the Year (2002)
Marquis Who's Who in Medicine and Healthcare (2002)
Family Practice Research Presentation Second Prize
"Alzheimer's disease increases the cost of comorbidities in managed care"
American Assocation of Family Practice (2001)
Recipient, The Rita Hayworth Physicians Award, Alzheimer's Association (1999)
Recipient, Geriatrics Recognition Award, American Geriatrics Society (2000-2004)
Recipient, Physicians Recognition Award, American Medical Association (1999-2002)
Fellow, The Gerontological Society of America (1998-present)
Fellow, The New York Academy of Medicine (1996-present)
Fellow, American Geriatrics Society (1992-present)
Fellow, American College of Physicians (1989-present)
Fellow, Gerontological Society of America (1998-present)
International Who's Who of Professionals (1998-1999)
Who's Who in Science and Engineering (1994-present)
Who's Who in Managed Health Care (1997-2002)
Who's Who in American Education (1995)
Who's Who in the World (1995)
Who's Who in the East (1994)
Who's Who in Health and Medical Services (1991)
Norman and Rosita Winston Fellow in Biomedical Research (1985-1987)
National Kidney Foundation Travel Award (1981); "Studies of Endothelial Cell Injury"
Beth Israel Medical Center Medical Residents Research Award (1975): "Immunologic studies of extracorporeal immunoadsorbents"
SUNY-Upstate Medical Center Research Scholarship (1971), "Neurobiological studies of learning in primates"
Cornell University Honors Program in Neurobiology Thesis Award (1970): "Conditioned drinking produced by angiotensin"
Cornell University Research Scholarship (1970), "The physiological psychology of thirst in man"
Phi Beta Kappa, Cornell University (1970)
Waldemar Medical Research Foundation Research Scholar (1965)

PROFESSIONAL SOCIETIES

American Association for the Advancement of Science (1981-2002, with lapses)
American College of Physicians (1980-present)

American Federation for Clinical Research (1987-1995)
American Geriatrics Society (1980-present)
Abstracts reviewer, American Geriatrics Society, 1997-1998
Member, Program Committee (2000-present)
Member, Research Committee (1999-present)
Section Chair, Neurobiological and Behavioral Sciences, Abstract Review Committee (2000-present)
American Medical Association (1985-1990)
American Society for Internal Medicine (1980-1990)
Association of University Technology Managers (2000-present)
Licensing Executive Society (2000-present)
The Gerontological Society of America (1980-present)
The New York Academy of Medicine (1996-present)
The New York Academy of Sciences (1999-present)
New York County Medical Society (1991-1994):
Member, Committee on Public Health (1994)
Member, Special Committee on Geriatrics (1991-1993)
Biotech Medical Management Association (1997-2001)
Member, Editorial/Journalism Committee (2000)

ADVISORY AND CONSULTANT POSITIONS

Corporate Board and Advisory Board Positions of Note

Chair, Scientific and Clinical Advisory Board, and Member of the Board (Observer), Neurotrax, Inc (New York, NY 2005-present)
Member, Scientific Advisory Board, Neuromolecular, Inc (San Diego, CA 2004-present)
Chair, Medical Advisory Board, Advanced Monitored Caregiving, NY NY (2003-present)
Member, Board of Directors (Observer), Zapaq, Inc, Oklahoma, OK (2003-present)
Member, Board of Directors (Observer) (2003-2004), and Member, Scientific Advisory Board (2003-present), Allon Therapeutics, San Diego CA
Chairman, Scientific Advisory Board, Neurochem, Inc. (2001-present)
Member, Scientific Advisory Board, Neurochem, Inc. (1997-2001)
Member. Advisory Board, Healthcare Dimensions, Inc., Phoenix AZ (2000-present)
Member, Medical Advisory Board, Memory Fitness Institute (2004-2005)

Biomedical Research

Member, Scientific Advisory Board, Alzheimer's Research and Education Consortium (2005)
Member, Scientific Advisory Board, Drug Discovery for Alzheimer's Disease, *Alzforum.Org* (2005-present)
Chair, Panel on Alternate Financing For Early Stage Biotechnology Companies, New York Biotechnology Association Annual Meeting (2005)
Member, Alzheimer's Disease National Adivsory Board, Pfizer-Eisai (2003-present)
Consultant, Sanofi-Aventis Pharmaceuticals (2005-2006)
Member, Advisory Board on Pharmacoeconomics, Elan Pharmaceuticials (2005)
Member, Editorial Advisory Board, Recent Patent Reviews CNS Drug Discovery, Bentham Press (2005-present)
Member, Scientific Advisory Board, Alzheimer's Research and Education Consortium (2005-present)
Member, Scientific Advisory Board, Carma Publishing (2005)
Member, Life Sciences Advisory Board, Cornell University (2004-present)
Member, Editorial Advisory Board, Aging Health (2005)
Member, Advisory Committee, New York Biotechnology Association (2004-2005)
Consultant, Astra-Zeneca Pharmaceuticals (2005)

Consultant, Pfizer National Advisory Board on Alzheimer's Disease (2004-2005)
Consultant, Sanofi-Synthelabo Pharmaceuticals (2004-2005)
Consultant, Aventis Pharmaceuticals (2004)
Consultant, Janssen Pharmaceuticals (2004)
Member, Advisory Board, Hadasit Medical Research and Development, Ltd. Jerusalem, Israel (2004-present)
International Scientific Committee for the forthcoming Fourth International Congress on Vascular Dementia, which is being held in Porto on October 20-23, 2005
Chair, Panel on Bench Meets Business: Focus on Alzheimer's disease, NY Biotechnology Association (2004)
Organizer and Chair, Panel on Alternative Financing for Early Stage Biotechnology Companies, BIO 2004 Annual meeting, San Francisco CA (2004)
Chair, Panel on Biotechnology and Alzheimer's disease, BIOInvestors 2004, New York, NY (2004)
Consultant, Program Committee, Member, (2003) Age Related Neurodegenerative Diseases Program Committee Meeting, The New York Academy of Sciences
Treasurer, Alzheimer's Research Consortium (2003)
International Scientific Committee, Third International Congress on Vacular Dementia (2003)
Consultant, Acorda Therapeutics (2002)
Member, Advisory Panel, "Neuroimaging for Alzheimer's Disease," sponsored by the National Institute on Aging (2002)
Member and Moderator, Advisory panel on "Long Term Use of Cholinesterase Inhibitors," Janssen Pharmaceuticals, Stockholm, Sweden (2002)
Chairman, Advisory panel on "Alzheimer's disease: Implications in managed care and long term care," Sanofi-Synthelabo, Chicago, IL (2002)
Member, International Organizing Committee, Second International Congress on Vascular Dementia, Salzburg, Austria (2002)
Member, Organizing Committee, First International Symposium on Alzheimer's disease in the Middle East (2001)
Member, Editorial Board, Section on Drug Discovery and Development, and Neurotechnology Journal of Molecular Neuroscience (2001)
Member, Perspectives in ERT/HRT Advisory Board, sponsored by Wyeth Ayerst (2000)
Reviewer, University-Industry Program, Canadian Institutes of Health Research (2000)
Reviewer, Grants Program, The Langeloth Foundation (2000)
Member, Professional Advisory Board, Alzheimer's Association, New York City (2000-present)
Reviewer, Alzheimer's Association Investigator-initiated Grant Program (2000)
Chairman, Grant Review Committee,
Program for Drug Discovery for Alzheimer's Disease in Academia,
American Federation for Aging Research (1999-present)
Consultants Committee, Women's Health Initiative Memory Study (WHIMS) (1997-present)
Member, National Scientific Advisory Council,
American Federation for Aging Research (1995-present)
Member, Drug Discovery Group Program, Ad Hoc Study Section,
National Institute on Aging (1996)
Consultant, Womens Health Research Insitute,
Wyeth Ayerst Laboraties, Philadelphia, PA (1995)
Consultant on Primary Prevention of Dementia, The Womans' Health Initiative,
Department of Public Health, Bowman Gray School of Medicine (1995)
Member, National Institute on Aging Ad Hoc Study Section,
Claude D. Pepper Older Americans Independence Centers (1995)
Reviewer Ad Hoc, Medical Reseach Council of Canada (1995)
Reviewer Ad Hoc, Sandoz Gerontology Foundation (1995-1996)
Scientific Consultant, Sandoz Pharmaceuticals Corporation, Basel, Switzerland (1992)
Scientific Consultant, Gliatech, Inc., Cleveland, Ohio (1992)
Ad Hoc Reviewer, Geriatric Academic Award Study Section,
National Insitute on Aging (1991-1992)

Health Care

Member, Steering Committee, 4th International Congress on the Pharmacoeconomics of Alzheimer's Disease Stockholm, Sweden, (2005)
Consultant, Pacificare Health Systems, Irvine CA (2005)
Consultant on patent issues related to Alzheimer's disease, Darby and Darby, NY NY (2004-2005)
Consultant and Expert Witness, Berger Kahn, Marina Del Ray, CA (2005)
Consultant, Pfizer Corporate Medical Affairs (European Programs) (2004)
Member, Women's Health Initiative Advisory Council (2001-present)
Member, Council of Healthcare Advisors (2001- present)
Member, Advisory Board, CareSteps (1999-2002)
Co-chairman, Clinical Advisory Board on Alzheimer's Disease,
The American Journal of Managed Care, NY, NY (2000)
Chairman, Clinical Advisory Board, For Health Inc., Costa Mesa CA (1998-2001)
Consultant, ExtendedCare.Com (2000-2001)
Member, Building Society, Aging in America (2000)
Expert peer reviewer (screening for dementia) (2000)
Research Triangle Institute-University of North Carolina
US Preventive Services Task Force, Agency for Health Care Research and Quality
Consultant on Medicare medical management, Physicians Weblink (2000-2001)
Consultant on Medicare medical management, Telesis Medical Management, Inc. (1999)
Consultant, Medicare medical management, For Health, Inc. (1999-2000)
Consultant on Medicare medical management,
Oxford Health Plans, White Plains, NY (1998-2000)
Editorial Board, Journal of Managed Care Medicine (1998-present)
Member, National Committee on Quality Assurance (NCQA)
Geriatric Measurement Advisory Panel, Expert Group on Geriatric Health, Workgroup on hip fractures (1998)
Member, Medicare Advisory Board, The Congress on Managed Medicaid and Medicare,
The National Managed Health Care Congress, Washington DC. (1997-1998)
Member, National Healthcare Advisory Board, U.S. Pharmaceuticals, Pfizer, Inc. (1997-1998)
Member, Managed Care Geriatrics Advisory Board, Merck Corporation (1997-1999)
Member, HMO Workgroup on Care Management, Chronic Care Initiatives in HMOs Program,
The Robert Wood Johnson Foundation and American Association of Health Plans (1996- 1999)
Member, Medicare Grievances and Appeals Work Group,
American Association of Health Plans, Washington, DC (1997)
Consultant on Geriatric Assessment in Managed Care,
Pilgrim Health Care-Harvard Community Health Plan, Boston Massachusetts (1995)
Member, Board of Directors, TelAssist Corporation, Ridgefield NJ (1996-1997)
Consultant on Geriatrics, AgeWave Health Services, San Francisco, California (1995)
Member, Medical Advisory Board on Sleep Disorders,
Searle Pharmaceuticals, Chicago, Illinois, 1994
Member, National Medical Advisory Committee, Sanus Health Care Corporation,
New York Life Insurance Corporation (1988-1995)
Consultant on Geriatrics, Technical Advisory Service for Lawyers, Phoenix, Arizona (1988-1995)
Consultant on Geriatrics, ExpertNet, Chicago, Illinois (1988-1995)
Member, Professional Advisory Board, American Friends of Sarah Herzog Memorial Hospital, Jerusalem, Israel (1990-1995)
Consultant on Geriatrics Program Development, The Englewood Hospital,
Englewood, New Jersey (1994)
Consultant on Geriatrics, GeriMed of America Corporation (1988-1992)

Consultant on Health Care for the Elderly (1985), United Health Care, Inc., Baltimore, Maryland
Advisory Council, Alternative Care Systems (1988)

Geriatric Medicine and Gerontology (Education and Public Policy)

Member, Advisory Panel, Business Briefings: Geriatrics Review 2006
Chair and Organizer, Program on Physical and Mental Activity and Cognitive Vitality, sponsored by the National Institutes of Health and the American Geriatrics Society (2005-2006)
Member, Older Adults Speakers Training Program, sponsored by the American Geriatrics Society
Member, Older Adults Caucus, sponsored by Pfizer (2005)
Member, Medicare Modernization Act speakers bureau, sponsored by Eden Communications and Pfizer (2005-2006)
Member, Research Committee, American Geriatrics Society (2005-2008)
Editorial Board, Aging Health (2005)
Editorial Advisory Board, The American Journal of Geriatric Pharmacotherapy (2003)
Member, Alzheimer's Association "Alois Alzheimer's Society" (2003-present)
Advisor, CME program on "The economic impact of Alzheimer's disease," sponsored by the Johns Hopkins University School of Medicine (2001)
Member, Board of Advisors, The Caregiving Project (1999-present)
Associate Editor, Geriatrics Review Syllabus, American Geriatrics Society (1999-present)
Senior Associate Member, International Longevity Center, New York, NY (1999-present)
Abstract Reviewer, Clinical Medicine Section, The Geronotological Society of America, (1999)
Chairman, Editorial Board, ElderCom, Pfizer, Inc., (1998-1999).
Co-Chair, Alzheimer's Disease Managed Care Advisory Council, Pfizer, Inc. (1997-2001)
Editorial Board, Frontiers in Bioscience (1995-present)
Editorial Board, Journal of Gerontology: Medical Sciences (1995- 1998)
Editorial Board, Alzheimer's Disease Newsletter, The Alzheimer's Disease Research Center, Mount Sinai Medical Center (1993-1995)
Editorial Board, GeriCom, Pracon, a subsidiary of Elsevier (1998-1999)
Editorial Board, Senior Sensitivity Training Program, Pfizer, Inc. (1998-1999)
Editorial Advisory Board, Senior Care Management, National Health Information, LLC (1998-present)
Member, Managed Care Advisory Board on Rheumatoid Arthritis, Wyeth Ayerst (1998)
Member, Medicare Graduate Medical Education Payment, Work Group, American Association of Health Plans, Washington, DC (1997)
Member, Advisory Board, Healthy Aging Newsletter, Merck Corporation (1997-1998)
Member, Advisory Panel, "How the standard Medicare program can be improved to better serve persons with chronic illness," sponsored by The Health Insurance Reform Project and *Health Affairs,* Washington DC (1997).
Member, Advisory Panel, "Developing practical measures for assessing quality of care at the end of life," Departments of Health Policy and of Geriatrics and Adult Development, Mount Sinai Medical Center, NY (1997)
Panel Member, "Requirements for effective chronic disease management," Robert Wood Johnson Foundation, Seattle WA (1996)
Consultant on Geriatrics, Life Sciences Communications, New Haven Connecticut (1995)
Ad Hoc Reviewer (Geriatrics), Allegheny-Singer Research Institute (1994)
Consultant, The International Senior Games, The Institute for International Sport, Hamilton, Bermuda, (1994-1995)
Consultant on Geriatric Assessment, SANDOZ Pharmaceuticals Corporation, Basel, Switzerland, (1993-1994)
Consultant in Geriatrics Training Programs, John A. Hartford Foundation (1991)
Consultant on Geriatrics, "Improved versus deteriorated physical functioning," National Institutes on Aging; Principal Investigator, Rachel Boaz, PhD, The Graduate School of the City University of New York (1991-2)
Member, Pharmacology (AHR-S1) Study Section Pharmacology in Geriatric Medicine, (1990)

Consultant, Utilization Review Committee, The Rockefeller University Hospital (1986-1987)
Adivsory Board, "Person to Person", Nova Productions Video Series (1987)
Physician Advisor (1981-1985), Professional Standards Review Organization,
Queens, New York
Consultant on Estrogen Replacement Therapy, Richard Weiner Public Relations (1987-1988)

Bibliography of over 250 original articles, books, monographs and abstracts available on request.

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Original Articles

1. Seligman, M.E.P., Mineka, S. and Fillit, H.M. 1971. Conditioned drinking produced by procaine, NaCl and angiotensin. J. Comp. Physiol. Psych. 77:110-121.

2. Fillit, H.M., Bernstein, M., Davidson, M., Brandt, L., Bezalher, G. and Cohen, M. 1977. Primary hypogammaglobulinemia and regional enteritis. Arch. Int. Med. 137:1252-1254.

3. Fillit, H.M., Read, S.E., Sherman, R.L., Zabriskie, J.B. and van de Rijn, I. 1978. Cellular reactivity to altered glomerular basement membrane in glomerulonephritis. N. Engl. J. Med. 298:861-868.

4. van de Rijn, I., Fillit, H.M., Brandeis, H., Reid, T., Poon-King, T., McCarty, M., Day, N.K. and Zabriskie, J.B. 1978. Serial studies of circulating immune complexes in poststreptococcal sequelae. Clin. Exp. Immunol. 34:318-325.

5. Zabriskie, J.B., Fischetti, V.A., van de Rijn, I., Fillit, H.M. and Villarreal, H., Jr. 1978. Biological implications of cross-reactions between Group A streptococci and renal tissues. In Biology and Chemistry of Basement Membranes, Kefalides, N.A., Editor, Academic Press, New York, pp. 453-462.

6. Zabriskie, J.B., Fillit, H.M. and Tauber, J.W. 1979. Streptococci and autoimmunity. In Sixth Int. Conv. Immunol. Karger, S., AG, Basel, Switzerland, Vol. 48, pp. 236-242.

7. Zabriskie, J.B., Fillit, H.M. and Villarreal, H., Jr. 1979. The relationship of group A streptococci and mammalian tissue antigens to certain disease states. Arch. Nat. Inst. Cardiol. Mexico 49:74-88.

8. van de Rijn, I., Fillit, H.M., Brandeis, W.E., Day, N.K. and Zabriskie, J.B. 1979. Serial studies on circulating immune complexes in acute rheumatic fever and acute poststreptococcal glomerulonephritis. In Protides of the Biological Fluids, Peeters, H., Editor, Pergammon Press, pp. 279-282.

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10. Fillit, H.M. 1981. Methods in Immunology. In Clinical Immunology of The Heart, Zabriskie, J.B., Villarreal, H., Jr., eds., Grune and Stratton, New York, pp. 1-22.

11. Fillit, H.M. and Villarreal, H., Jr. 1982. Methods in Immunology. In Clinical Immunology of The Kidney, Zabriskie, J.B., Fillit, H.M., Villarreal, H., Jr., and Becker, E.L., eds., Grune and Stratton, New York.

12. Fillit, H.M. and Zabriskie, J.B. 1982. Cellular immunity in glomerulonephritis. In Clinical Immunology of The Kidney, Zabriskie, J.B.,Fillit, H.M., Villarreal, H.,Jr., and Becker, E.L., eds., Grune and Stratton, New York.

13. Fillit, H.M. and Zabriskie, J.B. 1982. Cellular immunity in glomerulonephritis. Am. J. Path. 109:227-243.

14. Fillit, H.M., Jaffe, E.A. and Zabriskie, J.B. 1982. In vitro correlates of endothelial injury and repair. Lab. Invest. 46:1-9.

15. Fillit, H.M., Villarreal, H., Jr. and Zabriskie, J.B. 1982. The role of streptococcal and glomerular basement membrane antigens in glomerulonephritis. In Immune Mechanisms in Renal Disease, N. Cummings, A.F. Michael, and C.B.Wilson, eds. Plenum Press, pp. 399-418.

16. Fillit, H.M., Elion, E., Sullivan, J., Sherman, R.L. and Zabriskie, J.B. 1982. Thiobarbituric acid reactivity of uremic blood. Nephron 29:40-43.

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18. Hoffman, P., Marron, K.M., Fillit, H.M., and Libow, L.S. 1983. Obtaining informed consent in the teaching nursing home. J. Am. Geriat. Soc. 31:565-569.

19. Frocht, A. and H.M. Fillit. 1984. Renal disease in the elderly. J. Am. Ger. Soc. 32:28-43.

20. Fillit, H., and Zabriskie, J. B. 1984. Editorial: New concepts of glomerular injury. Lab. Invest. 51:117-120.

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poststreptococcal glomerulonephritis. In Recent Advances in Streptococci and Streptococcal Diseases, ed. by Y. Kimura, S. Kotami, and Y. Shiokawa, Reedbooks Ltd., Berkshire England, p. 253.

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31. Fillit, H.M. 1987. Book Review: Renal Function and Disease in the Elderly Ann. Int. Med. 107:129.

32. Kemeny, E., Fillit, H.M., Damle, S.P., Mahabir, R., Kefalides, N.A., Gregory, J.D., Antonovych, T., Sabnis, S., and Zabriskie, J.B. 1988. Monoclonal antibodies to heparan sulfate proteoglycan: development and application to the study of normal tissue and pathologic human kidney biopsies, Conn. Tiss. Res. 18:9-25.

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35. Foley, P., Bradford, H.F., Docherty, M., Fillit, H., Luine, V.N., McEwen, B., Bucht, G., Winblad, B., and Hardy, J. 1988. Evidence for the presence of antibodies to cholinergic neurons in the serum of patients with Alzheimer's disease. J. Neurol. 235:466-471.

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REVISED EXHIBIT B FOR OPENING EXPERT REPORT OF DR. HOWARD M. FILLIT

Documents

1. '318 Patent [JAN RAZ-0000001 - JAN RAZ-0000003]
2. Prosecution History of the '318 Patent as presented by the PTO [JAN RAZ-0000004 - JAN RAZ-0000256]
3. Defendant Alphapharm Pty., Ltd's Objections and Responses to Plaintiffs' Second Set of Interrogatories (Nos. 4-8).
4. Defendants Mylan Pharmaceuticals Inc.'s and Mylan Laboratories Inc.'s Objections and Responses to Plaintiffs' Second Set of Interrogatories (Nos. 4-8).
5. Defendants Teva Pharmaceuticals USA Inc.'s and Teva Pharmaceutical Industries Ltd.'s Objections and Responses to Plaintiffs' Second Set of Interrogatories (Nos. 4-9).
6. Paragraph IV Notice Filed by Alphapharm [JAN RAZ-0001032 - JAN RAZ-0001060]
7. Paragraph IV Notice Filed by Barr [JAN RAZ-0001061 - JAN RAZ-0001080]
8. Paragraph IV Notice Filed by Dr. Reddy's [JAN RAZ-0001002 - JAN RAZ-0001031]
9. Paragraph IV Notice Filed by Mylan [JAN RAZ-0000955 - JAN RAZ-0000976]
10. Paragraph IV Notice Filed by Par [JAN RAZ-0001081 - JAN RAZ 0001106]
11. Paragraph IV Notice Filed by Purepac [JAN RAZ-0000977 - JAN RAZ-0001001]
12. Paragraph IV Notice Filed by Teva [JAN RAZ-0000937 - JAN RAZ-0000954]
13. Deposition transcript of Dr. Bonnie Davis (February 8-9, 2006) and Exhibits
14. Deposition transcript of Dr. Kenneth Davis (February 14, 2006) and Exhibits
15. Johnson & Johnson Pharmaceutical Research & Development Medical Report, Justification for Claim that Galantamine Functions as an Allosteric Potentiating Ligand (APL) on Nicotinic Receptors at [JAN RAZ-0188028- JAN RAZ-0188042].

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